BRIEF SUMMARY OF THE INVENTION

[0014] An object of the present invention is to provide an obesity treatment that does not cause significant modifications to the patient's anatomy as compared to other surgical treatments. Another object of the present invention is to provide an obesity treatment whose parameters can be adjusted frequently to adjust the rate of weight loss. Another object of the present invention is to provide an obesity treatment whose parameters can be adjusted with minimal discomfort to the patient.

[0015] To achieve the foregoing objects, and in accordance with the purpose of the present invention, the present invention provides a device for causing weight loss in obese patients comprising an implant that creates an intestinal bypass between a first region of intestine and a second region of intestine. A part of food material passing through the intestine from the first region of intestine to the second region of intestine is diverted through the intestinal bypass. As the intestine is the main site for absorption of nutrients from food material, diversion of a part of food material through the bypass graft causes a reduction in the total nutrients absorbed by the body from the food material. This causes the patient to lose weight. In one embodiment, the implant comprises an adjustable opening to adjust the fraction of food material passing through the intestinal bypass and hence adjust the rate of weight loss.

[0016] The present invention also provides a method for causing weight loss in obese patients comprising the steps of surgically creating an intestinal bypass with an adjustable opening, calculating an expected weight loss and an expected electrolyte balance in the patient, periodically monitoring the patient's weight loss and electrolyte balance and adjusting the size of the adjustable opening if necessary.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The preferred embodiments of the invention will hereinafter be described in conjunction with the appended drawings provided to illustrate and not to limit the invention, where like designations denote like elements, and in which:

FIG. 1 illustrates the general working environment of the invention;

FIG. 2 illustrates an embodiment of the invention;

FIG. 3 illustrates a second embodiment of the invention;

FIG. 4 illustrates a third embodiment of the invention;

FIG. 5 illustrates a sectional view of an embodiment of the invention;

FIG. 6 illustrates an embodiment of the adjustable opening of the invention;

FIG. 7 illustrates a second embodiment of the adjustable opening of the invention; and

FIG. 8 illustrates the method of the present invention to achieve weight loss in obese patients.

DETAILED DESCRIPTION OF THE INVENTION

[0018] FIG. 1 illustrates the general working environment of the invention. The invention comprises an implant 100 that connects a first region 104 of the intestine to a second region 106 of the intestine to create an intestinal bypass. First region 104 is located on the small intestine. Second region 106 is located downstream from first region 104. Second region 106 can be located on the small intestine or the large intestine.

[0019] The invention achieves weight loss by reducing the amount of food material that is absorbed by the body. A portion of food material passing through the intestine from the first region 104 to the second region 106 is diverted through the intestinal bypass. The portion of food material passing through the intestinal bypass is unabsorbed. As the intestine is the main site for

absorption of the food material, diversion of a portion of food material through the intestinal bypass reduces the net food material absorbed by the body. This causes the patient to lose weight.

[0020] FIG. 2 illustrates an embodiment of the invention. The invention comprises an implant 200 that comprises a ring that directly connects a first region 202 of the intestine to a second region 204 of the intestine to create an intestinal bypass.

[0021] FIG. 3 illustrates a second embodiment of the invention. The invention comprises a tubular implant 300 that connects a first region 302 of the intestine to a second region 304 of the intestine to create an intestinal bypass. Tubular implant 300 comprises an adjustable opening 306 to adjust the rate of weight loss.

[0022] The rate of weight loss can be controlled by adjusting the size of adjustable opening 306. A larger opening will cause a greater portion of the food material to pass through the intestinal bypass. This will reduce the amount of nutrients absorbed by the intestine from the food material and thus increase the rate of weight loss. Similarly, reducing the size of adjustable opening 306 will reduce the rate of weight loss.

[0023] FIG. 4 illustrates a third embodiment of the invention. The invention comprises an implant 400 that comprises a ring that directly connects a first region 402 of the intestine to a second region 404 of the intestine to create an intestinal bypass. Implant 400 comprises an adjustable opening 406 to adjust the rate of weight loss.

[0024] FIG. 5 illustrates a sectional view of an embodiment of the invention. An intestinal bypass graft 500 is used to create a bypass between a first region 502 of the intestine and a second region 504 of the intestine. Intestinal bypass graft 500 comprises a tubular implant 506. Tubular implant 506 can be made of suitable biocompatible materials like silicone gel, polyurethane, ultra high molecular weight polyethylene, polyethylene terephthalate, polypropylene, polytetrafluoroethylene and polyamides. In one embodiment, the walls of the tubular implant are hollow and are filled with a filler material. Examples of filler material that can be used are silicon gel, saline, soybean oil, hydro gel, polyvinylprolidone, polyethylene glycol, and hyaluronic acid. The inner surface of tubular implant 506 has a series of projections. The projections help the flow of food material in the intestine in a single direction. One end of tubular implant 506 is connected to first region 502 of intestine by one or more fasteners 508 to create an end-to-side anastomosis.

Fasteners 508 are biocompatible. Examples of materials that can be used as fasteners 508 are sutures, clips, staples, screws, tags and adhesives. The other end of tubular implant 506 is connected to second region 504 of intestine by one or more fasteners 510 to create an end-to-side anastomosis. Fasteners 510 are biocompatible. Examples of materials that can be used as fasteners 510 are sutures, clips, staples, screws, tags and adhesives. Tubular implant 506 is provided with an adjustable opening 512. Adjustable opening 512 regulates the amount of food that passes through intestinal bypass graft 500. Increasing the size of adjustable opening 512 increases the amount of food passing through intestinal bypass graft 500. This reduces the amount of consumed food that is absorbed by the patient's body and increases the rate of weight loss. Similarly, reducing the size of adjustable opening 512 reduces the rate of weight loss. Thus the rate of weight loss can be regulated by changing the size of adjustable opening 512. Tubular implant 506 is further provided with an elastic mechanism 514. Elastic mechanism 514 provides elasticity to intestinal bypass graft 500. The motion of the patient and the peristaltic motion of the patient's intestines cause various regions of intestinal bypass graft 500 to move with respect to each other. This movement facilitates the flow of food material passing through intestinal bypass graft 500. In one embodiment, elastic mechanism 514 is in the form of a spring wound around tubular implant 506. Several biocompatible materials like titanium alloys, stainless steel alloys or elastic biocompatible polymers can be used for constructing the spring. Tubular implant 506 further comprises a valve 516. Valve 516 allows the flow of food material only in a single direction and thus prevents backflow of the food material. Valve 516 can be a mechanical valve or a bioprosthetic valve. Examples of mechanical valves that can be used are ball valves, single-leaflet (tilting disk) valves and bileaflet valves. They can be made of one or more biocompatible materials like collagen, stainless steel, titanium, pyrolytic carbon, Teflon or Dacron. Bioprosthetic valves can be made from animal or human tissues.

[0025] FIG. 6 illustrates an embodiment of the adjustable opening of the invention. The adjustable opening comprises an iris diaphragm 600. Iris diaphragm 600 comprises a base plate 602. Base plate 602 is annular in shape. Iris diaphragm 600 further comprises a plurality of blades 604. Each blade is attached to base plate 602 by a pivot in such a way that blades 604 enclose a lumen 606. Iris diaphragm 600 further comprises a blade actuating ring 608 attached coaxially to

base plate 602. Blade actuating ring 608 can rotate around its axis. Blade actuating ring 608 is provided with a plurality of slots 610. The number of slots on blade actuating ring 608 is equal to the number of blades attached to base plate 602. Each blade is provided with a projection 612. Projection 612 of each blade slides within a slot on blade actuating ring 608. Thus, each blade is pivoted on base plate 602 and communicates with blade actuating ring 608. Blade actuating ring 608 is further provided with a plurality of gripping slots 614. Gripping slots 614 are used in gripping and rotating blade actuating ring 608. Rotation of blade actuating ring 608 changes the orientation of blades 604. This changes the size of lumen 606. Thus, the size of adjustable opening in the invention can be changed by rotating blade actuating ring 608. In one embodiment, blade actuating ring 608 is rotated using endoscopic means. Several biocompatible materials like titanium alloys, stainless steel alloys or elastic biocompatible polymers can be used for constructing the iris diaphragm 600.

[0026] FIG. 7 illustrates a second embodiment of the adjustable opening of the invention. The size of the adjustable opening is controlled using electromagnetic signals. The adjustable opening comprises an iris diaphragm 700. Iris diaphragm 700 comprises a base plate 702. Base plate 702 is annular in shape. Iris diaphragm 700 further comprises a plurality of blades 704. Each blade is attached to base plate 702 by a pivot in such a way that blades 704 enclose a lumen 706. Iris diaphragm 700 further comprises a blade actuating ring 708 attached coaxially to base plate 702. Blade actuating ring 708 can rotate around its axis and can act a gear. Blade actuating ring 708 is provided with a plurality of slots 710. The number of slots on blade actuating ring 708 is equal to the number of blades attached to base plate 702. Each blade is provided with a projection 712. Projection 712 of each blade slides within a slot on blade actuating ring 708. Thus, each blade is pivoted on base plate 702 and communicates with blade actuating ring 708. The outer diameter of blade actuating ring 708 is geared to a driver gear 714. Driver gear 714 is connected to a control mechanism comprising a motor 716 and a controller 718 that supplies electric current to motor 716. Controller 718 is connected to a receiver 720. Receiver 720 receives electromagnetic signals and converts the received electromagnetic signals to electric signals and transmits the electric signals to controller 718. A battery 722 supplies electric energy to controller 718 and receiver 720.

[0027] Receiver 720 receives electromagnetic signals containing information about a required change in size of the adjustable opening. Receiver 720 converts the electromagnetic signals to electric signals and transmits the electric signals to controller 718. Controller 718 calculates the required electric current to cause the required change in size of the adjustable opening. The required electric current is then delivered to motor 716 causing driver gear 714 to rotate. Rotation of driver gear 714 causes blade actuating ring 708 to rotate. Rotation of blade actuating ring 708 changes orientation of blades 704. This changes the size of lumen 707. Thus, the size of adjustable opening in the invention can be changed. In one embodiment, controller 718, receiver 720 and battery 722 are implanted in the patient's body. The electromagnetic signals are generated out of the patient's body by an external remote controller. Thus, the size of the adjustable opening can be adjusted by a non-invasive procedure. Several biocompatible materials like titanium alloys, stainless steel alloys or elastic biocompatible polymers can be used for constructing the iris diaphragm 700.

[0028] FIG. 8 illustrates the method of the present invention to achieve weight loss in obese patients.

[0029] The method of the present invention is based on periodically monitoring the patient's physiological parameters and adjusting the size of the intestinal bypass opening. At step 802, the patient's initial physiological parameters are measured. Some examples of the physiological parameters that are measured are total weight, body mass index, concentration of blood glucose and electrolyte balance. Electrolyte balance is the balance of physiologically crucial compounds like vitamins, and serum electrolytes such as calcium, magnesium, iron and phosphate. Based on these physiological parameters, at step 804, a time is fixed for the followup of the patient. The aim of the followup is to monitor the patient's health status and the effectiveness of the weight loss method. At step 806, a desired weight loss is calculated based on the patient's physiological parameters. The desired weight loss is in the form of a range of weight loss that is desired in the patient until the followup. Also, at step 806, a desired electrolyte balance is calculated for the patient. A proper balance of electrolytes such as calcium, magnesium, iron and phosphate and of vitamin D is crucial for the normal functioning of the body. A poorly designed weight loss program can lead to an excessive loss of electrolytes from the body. At step

810, an initial bypass opening size is calculated based on the patient's physiological parameters, the desired weight loss and the desired electrolyte balance. At step 812, an intestinal bypass with an adjustable opening is surgically created in the patient. The size of the adjustable opening is the initial bypass opening size determined at step 810. Thereafter, the patient is discharged from the hospital and is asked to appear for followup at the time calculated at step 804. During the followup, at step 816, the patient's actual weight loss and actual electrolyte balance is measured. At step 818, the desired weight loss and the actual weight loss are compared. Also, at step 818, the desired electrolyte balance and the actual electrolyte balance are compared. If the desired weight loss and the actual weight loss are not comparable or if the desired electrolyte balance and the actual electrolyte balance are not comparable, the method proceeds to step 820. At step 820, a new bypass opening size is calculated. The calculation is done by taking into consideration the desired weight loss, the actual weight loss, the desired electrolyte balance and the actual electrolyte balance. At step 822, the intestinal bypass is adjusted to the new bypass opening size calculated at step 820. At step 824, a time is fixed for the followup of the patient. At step 826, a desired weight loss is calculated. The desired weight loss is in the form of a range of weight loss that is desired in the patient until the followup calculated at step 824. Also, at step 826, a desired electrolyte balance is calculated for the patient. Thereafter, the method proceeds to step 816.

[0030] Referring back to step 818, if at step 818, the desired weight loss and the actual weight loss are comparable and the desired electrolyte balance and the actual electrolyte balance are comparable, the method proceeds to step 824.

[0031] While the preferred embodiments of the invention have been described, it will be clear that the invention is not limited to these embodiments only. Several modifications, changes, variations, substitutions and equivalents will be apparent to persons skilled in the art without departing from the spirit and scope of the invention as described in the claims.

[0032] Obesity bypass device above mentioned can be coated with drugs such as antibiotics in order to reduce device related infections.